ATTACHMENT F-2

Attachment F-2 - Defendants' Witness List

Defendants incorporate their Supplemental Witness Disclosures served on the 18th of November, 2021 and attached hereto.

Defendants will have present at trial:

Robert Carr

May be contacted c/o Nelson Mullins Riley & Scarborough LLP 201 17th Street NW, Suite 1700, Atlanta, GA 30363 (404) 322-6000

Chad Modra

May be contacted c/o Nelson Mullins Riley & Scarborough LLP 201 17th Street NW, Suite 1700, Atlanta, GA 30363 404-322-6000

John DeFord*

May be contacted c/o Nelson Mullins Riley & Scarborough LLP 201 17th Street, NW, Suite 1700, Atlanta, GA 30363 (404) 322-6000

Shari O'Quinn*

Former employee of BPV May be contacted c/o Nelson, Mullins, Riley & Scarborough LLP 201 17th Street, Suite 1700, Atlanta, GA 30363

Piotr Sobieszczyk, M.D.

Cardiovascular Division Vascular Medicine Section Brigham and Women's Hospital 75 Francis Street Boston, MA 02115

David Fischman, M.D.

Jefferson Angioplasty Center 111 S. 11th Street, Suite 6210 Gibbon Building Philadelphia, PA 19107

Christine Brauer, Ph.D.**

Brauer Device Consultants, LLC 7 Trail House Court Rockville, Maryland 20850

Paul Briant, Ph.D., P.E.

Exponent 149 Commonwealth Drive Menlo Park, CA 94025

David Feigal, M.D.

11806 Barranca Road Santa Rosa Valley, CA 93012

Clement Grassi, M.D.

18 Sussex Road Winchester, MA 01890

Donna-Bea Tillman, Ph.D.**

Brauer Device Consultants, LLC 7 Trail House Court Rockville, Maryland 20850

Defendants may have present at trial:

Murray Asch, M.D.*

66 Downey Drive Brooklin, Ontario L1M1J6

Richard Bliss*

Former employee of Bard May be contacted c/o Nelson Mullins Riley & Scarborough LLP 201 17th Street, NW, Suite 1700, Atlanta, GA 30363

Andre Chanduzsko*

Current employee of BPV May be contacted c/o Nelson Mullins Riley & Scarborough LLP 201 17th Street, NW, Suite 1700, Atlanta, GA 30363

David Ciavarella*

Current employee of Bard May be contacted c/o Nelson Mullins Riley & Scarborough LLP 201 17th Street, NW, Suite 1700, Atlanta, GA 30363

Bill Cleary*

May be contacted c/o Nelson Mullins Riley & Scarborough LLP 201 17th Street, NW, Suite 1700, Atlanta, GA 30363 (404) 322-6000

Mary Edwards*

May be contacted c/o Nelson Mullins Riley & Scarborough LLP 201 17th Street, NW, Suite 1700, Atlanta, GA 30363 (404) 322-6000

Tom Ferari*

Former employee of C. R. Bard May be contacted c/o Nelson Mullins Riley & Scarborough LLP 201 17th Street, NW, Suite 1700 Atlanta, GA 30363

Christopher Ganser*

Former employee of C. R. Bard May be contacted c/o Nelson Mullins Riley & Scarborough LLP 201 17th Street, NW, Suite 1700 Atlanta, GA 30363

Janet Hudnall*

Former employee of BPV May be contacted c/o Nelson Mullins Riley & Scarborough LLP 2017 17th Street, NW, Atlanta GA 30363

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Alex Tessmer*

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Consultant to BPV

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Natalie Wong*

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Christopher Morris, M.D.

Department of Radiology The University of Vermont Medical Center 111 Colchester Avenue Burlington, VT 05401

Ronald Thisted, Ph.D.

Office of the Provost The University of Chicago Levi Hall, Room 432 5801 South Ellis Avenue Chicago, Illinois 60637

Pooja Bardhan, M.D.

Georgia Cancer Specialists Administrative Annex 1835 Savoy Drive Atlanta GA 30341

Arum Chervu, M.D.

Vascular Surgical Associates 61 Whitaker Street Suite 2100 Marietta, GA. 30060

Stephanie Eaton, M.D.*

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Jason Levy, M.D.*

Northside Radiology 1000 Johnson Ferry Rd. Atlanta, GA 30342

John Murray, M.D.

Emory Pulmonology Clinic 555 Peachtree St Medical Office Tower Floor 15 Atlanta, GA 30308

John Puskas, M.D.*

Icahn School of Medicine at Mount Sinai Beth Israel Hospital 1111 Amsterdam Ave New York, NY 10025

John Sparti. D.O.*

Dallas Family Practice Center 318 Main St Dallas, GA 30132

All witnesses identified by Plaintiff.

^{*}This witness may testify live or by designated deposition or prior trial testimony.

^{**} Bard will only call one regulatory expert and will identify which one at least 10 days prior to trial

IN THE UNITED STATES DISTRICT COURT FOR THE NORTHERN DISTRICT OF GEORGIA ATLANTA DIVISION

JENNIFER R. COKER

Plaintiff,

v.

Civil Action No. 1:13-CV-00515-TWT

C. R. BARD, INC., and BARD PERIPHERAL VASCULAR, INC.,

Defendants.

<u>DEFENDANTS C.R. BARD, INC.'S AND</u> <u>BARD PERIPHERAL VASCULAR, INC.'S SUPPLEMENTAL RULE 26</u> WITNESS DISCLOSURES

Pursuant to Fed. R. Civ. P. 26 Defendants C. R. Bard, Inc. ("C. R. Bard") and Bard Peripheral Vascular, Inc. ("BPV") (collectively "Defendant(s)" or "Bard") supplement their disclosure of witnesses. This case was pending prior to the filing of the MDL, *In re Bard IVC Filters Prods. Liab. Litig.*, MD-15-02641-PHX-GDC ("MDL") during which many witnesses were identified, depositions were taken and trials were conducted. Plaintiff, by and through her counsel of record, including her counsel who is chairperson of the Plaintiffs' Steering Committee in the MDL, has access to all of those depositions and all trial testimony.

- I. <u>Fact Witnesses who have information that Bard may use to support</u> its defenses.
 - 1. Jennifer Coker Plaintiff

2. Joel Coker

3. Any and all of Ms. Coker's health care providers or professionals, including but not limited to:

Stephanie Eaton, M.D.

Pulmonary & Critical Care of Atlanta 960 Johnson Ferry Road NE Suite 500 Atlanta, GA 30342

Paul Boyce, M.D.

Pulmonary & Critical Care of Atlanta 960 Johnson Ferry Road NE Suite 500 Atlanta, GA 30342

Howard Silverboard, M.D.

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Northside Radiology 1000 Johnson Ferry Rd. Atlanta, GA 30342

John Puskas, M.D.

1111 Amsterdam Ave New York, NY 10025

Pooja Bardhan, M.D.

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Kristina Bowen, M.D.

Georgia Cancer Specialists Administrative Annex 1835 Savoy Drive Atlanta GA 30341

Lynn Zemsky, M.D.

Georgia Cancer Specialists Administrative Annex 1835 Savoy Drive Atlanta GA 30341

Arum Chervu, M.D.

Vascular Surgical Associates 61 Whitaker Street Suite 2100 Marietta, GA. 30060

John Sparti, D.O.

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Wissam Jaber, M.D.

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Sriram Paramesh, M.D.

Piedmont Physicians Pulmonary & Sleep Medicine of Marietta 660 Cherokee Street Northeast, Suite 200 Marietta, GA 30060

Preethi Natarajan, M.D.

Douglas Neurology Associates 4586 Timber Ridge Dr. Douglasville, GA 30135

Lee Brian Padove, M.D.

Northside Cardiology 1000 Johnson Ferry Rd Atlanta, GA 30342

Paul Sutej, M.D.

980 Jonson Ferry Rd. Suite 220 Atlanta, GA 30342

Sharon K Rim, M.D.

Northside Hospital Radiology 1000 Johnson Ferry Rd Atlanta, GA 30342

Praveen Reddy, M.D.

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Mujeeb Jan M.D.

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John Maloney, M.D.

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Blake Spain, M.D.

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Alan Plummer, M.D.

Emory Healthcare 1365 Clifton Rd. Atlanta, GA 30322

Phyllis Tong, M.D.

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David Finkleman, M.D.

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Hector Dourron, M.D.

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Aaron Cann, M.D.

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Jay S. Miller, M.D.

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Neal Osborn, M.D.

Atlanta Gastroenterology 144 Bill Carruth Parkway Suite 3600 Hiram, GA 30141

Vineet Dua, M.D.

144 Bill Carruth Parkway Suite 4200 Hiram, GA 30141

Rohit Panchal, M.D.

Cherokee Lung & Sleep Associates 55 Whiticher St. NE Marietta, GA 30060

David Fowler, M.D.

5555 Peachtree Dunwoody Rd. Suite 101 Atlanta, GA 30342

- **4.** Any and all individuals with knowledge of Ms. Coker's health history.
- **5.** Any and all individuals designated as witnesses by Plaintiff.
- **6.** Any individuals identified by the parties or in documents produced by other parties in initial disclosures or other discovery responses.

7. Shari O'Quinn (formerly Shari Allen)

Former employee of BPV May be contacted c/o Nelson, Mullins, Riley & Scarborough LLP 201 17th Street, Suite 1700, Atlanta, GA 30363

See description below.

8. Murray R. Asch, M.D.

66 Downey Drive Brooklin, Ontario L1M1J6 Dr. Asch is an interventional radiologist with Lakeridge Health Corporation in Ontario, Canada. He attended medical school at the University of Western Ontario. After graduation from medical school, he completed an internship and a two year residency program in internal medicine before being accepted into the radiology residency program in Toronto. After completing a four-year residency program in radiology, he completed an additional one-year fellowship program in interventional radiology, also in Toronto. Dr. Asch has had additional training and experience as reported on his curriculum vitae and has also served as president of the Canadian Interventional Radiology Association.

Dr. Asch has been involved in studies involving IVC filters. Dr. Asch was the principal investigator in a study regarding the evaluation of the use of the Recovery® Filter in humans. See Asch, M. R., Initial Experience in Humans with a New Retrievable Inferior Vena Cava Filter, Radiology 225(3): 835-844 (Dec. 2002). He may discuss the approval process for this study through the Canadian authorities and his hospital, as well as the purpose of the study, its protocol, and its outcome. He may also testify regarding his clinical research and experience with IVC filters in general and specifically with Bard's IVC filters. He may testify regarding his relationship and interactions with Bard, and more particularly with Robert Carr. He may testify about his role and motivation in presenting at seminars and otherwise training other physicians regarding the use of Bard's IVC filters, including but not

limited to live case demonstrations. Dr. Asch may testify live or by deposition consistent with his prior deposition testimony and trial testimony in the MDL.

Additionally, Dr. Asch may testify regarding the history of IVC filters and his clinical experience with IVC filters such as his experience with placing and retrieving IVC filters, as well as indications for IVC filters. He may also testify regarding the advantages of retrievable IVC filters. He may also discuss the benefits, risks, and potential complications of IVC filters, such as migration, fracture, tilting, and penetration, and the imaging and other evaluation of those events and their clinical significance, if any. He may also testify regarding his personal experience of observing only one fracture of a Bard IVC filter.

9. Richard Bliss

Former employee of Bard May be contacted c/o Nelson Mullins Riley & Scarborough LLP 201 17th Street, NW, Suite 1700, Atlanta, GA 30363

Mr. Bliss is a former employee of C. R. Bard, Inc., who also performed consulting work for BPV from 2004-2005 in a quality and regulatory role. subsequent to his departure from the company. Mr. Bliss was deposed in this case, and may testify live or by deposition consistent with his prior deposition testimony.

10. Robert Carr

Current employee of Bard Biopsy Systems
May be contacted c/o Nelson Mullins Riley & Scarborough LLP
201 17th Street, NW, Suite 1700, Atlanta, GA 30363

See description below.

11. Andre Chanduszko

Current employee of BPV May be contacted c/o Nelson Mullins Riley & Scarborough LLP 201 17th Street, NW, Suite 1700, Atlanta, GA 30363

See description below.

12. David Ciavarella, M.D.

Current employee of Bard May be contacted c/o Nelson Mullins Riley & Scarborough LLP 201 17th Street, NW, Suite 1700, Atlanta, GA 30363

Dr. Ciavarella is an employee of C. R. Bard, who has worked for Bard since 2004. He graduated from the School of Medicine at the University of California, Los Angeles in 1977. After medical school, he did his residency in internal medicine at Roosevelt Hospital in New York City and his fellowship in hematology at Roosevelt Hospital and at the University of Washington. He is board certified in internal medicine, hematology, and transfusion medicine. He is currently Vice President, Corporate Clinical Affairs at Bard, and he has held that title since he began working for Bard. In this role, Dr. Ciavarella has been involved with and has personal knowledge of Bard's broad policies and practices concerning its IVC filters, including, but not limited to, the company's clinical affairs and medical affairs. In this regard, Dr. Ciavarella may testify concerning how such policies and practices were developed, implemented, and reviewed. Dr. Ciavarella may testify live or by deposition consistent with his deposition testimony.

Dr. Ciavarella may testify concerning any and all aspects of Bard's clinical affairs policies, procedures, and practices that are, or have been, in place with respect to Bard's IVC filters. Such testimony may include, but is not limited to, discussion of Bard's policies, procedures, and practices concerning any clinical trial involving Bard's IVC filters, including the EVEREST Study. In this regard, Dr. Ciavarella may testify regarding the selection and clearance process for securing investigators and investigation sites, the creation and development of the study protocol, the creation and development of the informed consent form, and the steps taken by Bard to ensure that the study ran properly and according to Bard and FDA guidelines.

Dr. Ciavarella may also testify concerning any and all aspects of Bard's medical affairs policies, procedures, and practices that are, or have been, in place with respect to Bard's IVC filters. Such testimony may include, but is not limited to, discussion of Bard's policies, procedures, and practices concerning failure mode analyses. In this regard, Dr. Ciavarella may testify concerning Bard's efforts to analyze and understand potential medical implications of certain complications involving IVC filters, including, but not limited to, fracture, migration, and perforation. He may also testify regarding Bard's analysis and understanding of the clinical impact of these complications. In this regard, he may testify concerning the sources of information utilized by Bard to investigate, analyze, and understand, to the extent possible, such clinical impact of such complications. Additionally, Dr.

Ciavarella may testify regarding the effect, if any, that in-dwell time may have on the incidence of fracture in filters. Such testimony may include discussion and analysis of medical literature and anecdotal reports on this topic.

Dr. Ciavarella may also testify concerning Bard's policies, procedures, and practices that are, or have been, in place with respect to Bard's IVC filters with respect to its Health Hazard Evaluations. In this regard, Dr. Ciavarella may testify concerning how, when, and why Bard decides to conduct such evaluations and the policies, procedures, and practices related to such evaluations. Dr. Ciavarella may also testify concerning what actions, if any, Bard took in response to such evaluations.

Dr. Ciavarella may also testify regarding Bard's remedial action decisions. In this regard, Dr. Ciavarella may testify concerning the policies that guide such decisions and the practices undertaken and approved by Bard, including, but not limited to, product holds, the revision of the IFU for the Recovery® Filter, the dissemination of a Dear Doctor Letter in 2004, and the dissemination of a Dear Colleague Letter in 2005.

Based on reports received by Bard, Dr. Ciavarella may also testify concerning the rates of complications with Bard's IVC filters and analyses performed by Bard regarding adverse event rates. Dr. Ciavarella may also testify that the complication

rates reported to Bard remain below the guidelines established by the Society of Interventional Radiologists and Bard's action limits.

Dr. Ciavarella may also testify concerning his role in reviewing FDA submissions and promotional materials to ensure that such submissions and materials were medically accurate. In this regard, Dr. Ciavarella may testify concerning any and all recommendations he made concerning such submissions and materials.

13. Bill Cleary

May be contacted c/o Nelson Mullins Riley & Scarborough LLP 201 17th Street, NW, Suite 1700, Atlanta, GA 30363 (404) 322-6000

Mr. Cleary is a former employee of BPV. He worked as a territory manager from 2003 to 2008. He was deposed in this case and is expected to testify consistent with his deposition testimony.

14. Len DeCant

May be contacted c/o Nelson Mullins Riley & Scarborough LLP 201 17th Street, NW, Suite 1700, Atlanta, GA 30363 (404) 322-6000

Mr. DeCant was Vice President of Research & Development for BPV from 2002-2007. Mr. DeCant may testify about BPV's policies and procedures in place for its research and development of its products, including filters. He may testify regarding the fact that at the time Bard's retrievable IVC filters was were developed

and first sold, and even today, there is a dearth of scientific information about the internal functioning of the IVC.

Additionally, he may also testify regarding the fact that in the medical literature and medical community it is understood that all IVC filters carry with it certain risks including the risk of fracture and migration such that each doctor is to weigh the risks and benefits of implanting the device based on each individual patient's medical condition and treatment needs. The fracture, migration, perforation, and embolization rates of Bard's commercially available filters remain below the guidelines established by the Society of Interventional Radiologists and Bard's action limits. Upon receiving reports of fracture and migration, Bard was and has been proactive in investigating those reports and analyzing whether the risk of complications for its products is in line with industry standards, which it is and always has been. He may also testify that Bard kept the FDA abreast of the information it has about complications and complication rates with its IVC filters. In fact, the FDA has praised Bard for its openness and transparency in sharing information about its products.

He may also testify regarding the evolution of the Bard filters, including the fact that Bard is constantly evaluating the medical devices it sells, and it is constantly striving to improve the performance of those devices. In addition, he may also testify regarding the consideration Bard gave to the issue that surface conditions may have

played a role in filter fractures, including a discussion of testing Bard conducted to attempt to determine whether surface condition played any role in fracture. Such testing included fatigue testing, clinical testing, SEM review, material qualifications, and product verification testing including delivery, radial force, and fatigue testing.

Mr. DeCant may further testify about the procedures followed by Bard to inspect and confirm the quality of the various materials (including nitinol wire) used to manufacture the IVC filters. He may also testify regarding Bard's processes for verifying the integrity and design of component parts and products supplied by various other companies, Bard's materials verification processes, the selection and auditing of vendors, routine testing done as part of the manufacturing process, internal and external audits of Bard's plants, and the manufacturing plant's role in product complaint investigation. He may also provide testimony that was the subject of his previous deposition testimony.

15. John DeFord, Ph.D.

May be contacted c/o Nelson Mullins Riley & Scarborough LLP 201 17th Street, NW, Suite 1700, Atlanta, GA 30363 (404) 322-6000

See description below

16. Mary Edwards

May be contacted c/o Nelson Mullins Riley & Scarborough LLP 201 17th Street, NW, Suite 1700, Atlanta, GA 30363 (404) 322-6000

Ms. Edwards is BPV's former Vice President for Regulatory/Clinical Affairs.

Ms. Edwards was involved with and has personal knowledge of the regulatory

clearance process undertaken by BPV for the Recovery® Filter including the 510(k) processes and actions taken by BPV. Additionally, Ms. Edwards may testify concerning BPV's overall regulatory strategy for its filter lines, including the regulatory approach taken by BPV concerning the Recovery® Filter. In addition, Ms. Edwards may also testify concerning other regulatory options considered by BPV when it determined the best approach to gain FDA clearance for its new product. Ms. Edwards may testify regarding the regulatory history of Bard's filters, communications between the FDA and BPV concerning the Recovery® Filter, the clearance process for the Recovery® Filter, and post-clearance communications BPV had with the FDA while she was employed with BPV.

Ms. Edwards may also testify regarding BPV's representations made to the FDA while it was attempting to gain clearance for the Recovery® Filter, including but not limited to representations regarding fatigue resistance, fracture and migration rates, tilt and perforation resistance, and other potential known risks associated with all inferior vena cava filters. In this regard, Ms. Edwards may also testify concerning BPV's decision- making process in making these representations, including BPV's analysis regarding whether such representations were accurate and adequate. Ms. Edwards may also testify concerning BPV's communications with the FDA regarding reported complications with the Recovery® Filter. Ms. Edwards may also

testify concerning the internal process that BPV undertook to determine when it was appropriate to make such contact with the FDA.

Moreover, Ms. Edwards may also testify concerning any other communication between the FDA and BPV during the period in which Ms. Edwards worked at BPV, to the extent that she has personal knowledge of such communications. Ms. Edwards may also testify regarding the steps that BPV took to ensure that the FDA was always abreast of complications, product improvements, and potential changes to IFUs for the Recovery® Filter and G2® Filter. In this regard, Ms. Edwards may testify regarding BPV's open and frank communications with the FDA and the FDA's appreciation for BPV's openness and honesty. Ms. Edwards may also testify regarding BPV's decision to revise the IFU for the Recovery® Filter and to disseminate a Dear Doctor Letter in 2004.

Ms. Edwards may also testify concerning BPV and Bard's strong corporate policy against off-label marketing. In this regard, Ms. Edwards may testify regarding the measures undertaken by BPV and Bard to ensure that employees of the corporations did not market any product off-label. Moreover, Ms. Edwards may also testify concerning specific actions taken by BPV and Bard if and when they discovered off-label marketing.

Ms. Edwards may also testify concerning BPV and Bard's policies concerning monetary gifts and agreements to fund medical studies. She may also testify

concerning how these policies reflect BPV and Bard's resolve to ensure that any gift or agreement complies with federal regulations. She may also provide testimony that was the subject of her previous deposition testimony.

17. Tom Ferari

Former employee of C. R. Bard May be contacted c/o Nelson Mullins Riley & Scarborough LLP 201 17th Street, NW, Suite 1700 Atlanta, GA 30363

Mr. Ferari is a former employee of Bard and consultant who provided assistance in the manufacturing processes of certain products manufactured by Bard including IVC filters. He was deposed in this case and is expected to testify consistent with his deposition.

18. Christopher Ganser

Former employee of C. R. Bard May be contacted c/o Nelson Mullins Riley & Scarborough LLP 201 17th Street, NW, Suite 1700 Atlanta, GA 30363

Mr. Ganser is a former employee of C. R. Bard, who had worked for Bard from 1989 until his retirement in 2011. He has held various positions while working for Bard, including Quality Control Manager at a Bard plant in South Carolina; Manager for Bard Urological Division ("BUD"), Quality Control Operations; Director of Quality Assurance for BUD; Vice President of Quality Assurance; and Vice President of Quality Assurance and Environmental Services and Safety. In these roles, Mr. Ganser was involved with and has personal knowledge of Bard's broad and overarching policies and practices concerning its IVC filters, including,

but not limited to, the company's business practices, quality control policies and procedures, field assurance practices, complaint investigation, remedial action plans, and registration and management of products. In this regard, Mr. Ganser may testify concerning how such policies, procedures, and practices were developed, implemented, and reviewed. Mr. Ganser was deposed in a separate action involving claims related to Bard's IVC filters on February 28, 2011. Mr. Ganser may testify live or by deposition consistent with his deposition testimony.

Mr. Ganser may also testify concerning any and all aspects of Bard's quality control and field assurance practices and procedures that are, or have been, in place with respect to Bard's IVC filters. Such testimony may include, but is not limited to, discussion of Bard's policies, processes, and procedures for adverse complaint handling, complaint investigation, trending analysis, root cause analysis, data integrity audits, failure investigation reporting, and design failure mode analysis relating to Bard's IVC filters.

Based on reports received by Bard, Mr. Ganser may also testify concerning the rates of complications with Bard's IVC filters and analyses performed by Bard regarding adverse event rates. Mr. Ganser may also testify that the complication rates reported to Bard remain below the guidelines established by the Society of Interventional Radiologists and Bard's action limits.

Mr. Ganser may also testify regarding Bard's remedial action decisions. In this regard, Mr. Ganser may testify concerning the policies that guide such decisions and the practices undertaken and cleared by Bard, including, but not limited to, product holds, the revision of the IFU for the Recovery® Filter, the dissemination of a Dear Doctor Letter in 2004, and the dissemination of a Dear Colleague Letter in 2005.

Mr. Ganser may also testify concerning the evolution of the Bard IVC filters, including the fact that Bard is constantly striving to improve the design and performance of those devices. He may testify that, upon receiving reports of adverse events, Bard was, and has been, proactive in investigating those reports and analyzing whether the risk of such adverse event for its product is in line with industry standards and guidelines.

19. Janet Hudnall

Former employee of BPV May be contacted c/o Nelson Mullins Riley & Scarborough LLP 2017 17th Street, NW, Atlanta GA 30363

Ms. Hudnall is a former employee of BPV who worked for BPV from 1998 to 2008. While at BPV, Ms. Hudnall held various positions, including Product Development Engineer, Senior Product Manager, Marketing Manager, and Senior Marketing Manager. In those roles, Ms. Hudnall was involved with and has personal knowledge of, among other things, BPV's marketing strategies, policies, and practices with regard to the Bard's IVC filter line of products. Ms. Hudnall was

deposed in a separate action involving claims related to Bard's IVC filters on November 3, 2010. Ms. Hudnall may testify live or by deposition consistent with her deposition testimony.

Ms. Hudnall may testify concerning BPV's marketing strategies, policies, and practices with regard to the Recovery® and G2® Filters. In this regard, Ms. Hudnall may testify concerning the training offered by BPV to its sales force and the reasons and motivations underlying that training. Moreover, Ms. Hudnall may testify concerning the factual representations made by BPV in its marketing materials, including, but not limited to, BPV's representations regarding the safety and effectiveness of the filter, the known risks associated with the filter, the rate of complications such as fracture, migration, perforation, and tilt, and any enhancements made to the filter. Ms. Hudnall may also testify concerning BPV's policies and practices with regard to its marketing efforts toward specific hospitals and/or physicians. She may also testify concerning BPV's policies and procedures with regard to its attempts to obtain physician input regarding the filters in order to develop future generations of the product. Ms. Hudnall may also testify regarding how BPV processed and used such information to develop its product.

Ms. Hudnall may also testify concerning the training provided by BPV to physicians to familiarize them with the implantation and retrieval of the G2® Filter. In this regard, Ms. Hudnall may testify regarding the purpose and formulation of the

training program, the selection process for the trainers and trainees, the frequency of the training classes, the training methods and materials, and, if applicable, the certification or recognition of training completion given to physicians that completed the training offered.

Ms. Hudnall may also testify concerning BPV and Bard's strong corporate policy against off-label marketing. In this regard, Ms. Hudnall may testify regarding the measures undertaken by BPV and Bard to ensure that employees of the corporations did not market any product off-label. Moreover, Ms. Hudnall may also testify concerning specific actions taken by BPV and Bard if and when they discovered off-label marketing. Ms. Hudnall may also testify concerning how BPV reviewed and analyzed proposed marketing materials in order to ensure that such materials did not violate off-label marketing regulations.

Ms. Hudnall may also testify concerning BPV's practices and policies regarding complaints that were communicated by users. In this regard, Ms. Hudnall may testify regarding the steps taken by BPV, if a user communicated a complaint directly to a marketing or sales representative, to ensure that BPV adhered to federal reporting requirements. Moreover, Ms. Hudnall may testify regarding other procedures and policies undertaken by BPV to gather data regarding complications to the filter products, including, but not limited to, fracture, migration, perforation, and tilt. In this regard, Ms. Hudnall may testify about communications between BPV

and physicians concerning any complications and BPV's actions in response to such complications. Ms. Hudnall may also testify concerning other steps taken by BPV to ensure that it could appropriately respond to complications.

Ms. Hudnall may also testify regarding BPV's decision to revise the IFU for the Recovery® Filter and to disseminate a Dear Doctor Letter in 2004. In this regard, Ms. Hudnall may testify concerning BPV's actions to inform its sales force of the nature of the Dear Doctor Letter, the recipients of the Dear Doctor Letter, and the appropriate response that members of the sales force were to provide when faced with inquiries from users. Moreover, Ms. Hudnall may testify concerning BPV's internal decision-making process regarding if or when to remove the Recovery® Filter off the market. In this regard, Ms. Hudnall may testify concerning the considerations that BPV analyzed in formulating its decision.

Ms. Hudnall may also testify concerning BPV and Bard's policies and practices concerning monetary gifts and agreements to fund medical studies. She may also testify concerning how these policies reflect BPV and Bard's resolve to ensure that any gift or agreement complies with federal regulations. Furthermore, Ms. Hudnall may testify regarding any other practice, procedure, or policy undertaken by BPV in which BPV provided appropriate compensation to physicians for consulting and other services provided by such physicians.

Ms. Hudnall may also testify concerning BPV's decision to conduct a clinical trial, called the EVEREST Study, and issues and events associated with or related to the EVEREST Study. In this regard, Ms. Hudnall may testify concerning the selection and clearance process for securing investigators and investigation sites, the creation and development of the study protocol, the creation and development of the informed consent form, and the steps taken by BPV to ensure that the study ran properly and according to established guidelines.

20. John Lehmann, M.D.

May be contacted c/o Nelson Mullins Riley & Scarborough LLP 201 17th Street, NW, Suite 1700, Atlanta, GA 30363 404-322-6000

Dr. Lehmann is a former employee of C. R. Bard, Inc., who also performed consulting work for C. R. Bard, Inc. subsequent to his departure from the company. Dr. Lehmann and may testify live or by deposition consistent with his prior deposition testimony.

21. John McDermott

Former employee of BPV May be contacted c/o Nelson Mullins Riley & Scarborough LLP 2017 17th Street, NW, Atlanta GA 30363

Mr. McDermott is a former employee of Bard. In 1996, he joined Bard as President of IMPRA, a division of Bard. Later, he also served as President of Global Sales for IMPRA and Bard Peripheral Technologies. In 2002, Mr. McDermott assumed the position of President of BPV, and he held that position until 2007. In

these roles, Mr. McDermott was involved with and has personal knowledge of much of the day-to-day business activities of the companies. Mr. McDermott may testify live or by deposition consistent with his deposition testimony.

Additionally, Mr. McDermott may testify concerning IMPRA and BPV's broad and overarching policies concerning the Recovery® and G2® Filters, including, but not limited to, the companies' business practices, research and development, manufacturing, marketing and sales policies, and regulatory strategies and policies. In this regard, Mr. McDermott may testify concerning how such policies were developed, implemented, and reviewed.

Mr. McDermott may also testify concerning IMPRA and BPV's general business practices, policies, and strategies. In this regard, Mr. McDermott may testify regarding the considerations that IMPRA and BPV analyzed when they developed and sold their filter line of products. This may include, but is not limited to, considerations regarding available technology, feasibility, efficacy and utility, cost, and market perception.

Mr. McDermott may also testify concerning IMPRA and BPV's research and development strategies, policies, and practices. This testimony may include, but is not limited to, the proactive steps taken by IMPRA and BPV to respond to reported filter complications, including fracture, migration, tilt, and perforation. In this regard, Mr. McDermott may testify concerning IMPRA and BPV's efforts to

rigorously test and improve their products. Thus, Mr. McDermott may provide testimony concerning IMPRA and BPV's efforts to utilize the most advanced technology in order to provide the best product possible. Moreover, Mr. McDermott may testify concerning IMPRA and BPV's actions taken to ensure the safety and effectiveness of the Recovery® Filter and G2® Filter as permanent and retrievable devices.

Mr. McDermott may also testify concerning IMPRA and BPV's marketing strategies, policies, and practices with regard to the Recovery® Filter and G2® Filter. In this regard, Mr. McDermott may testify regarding IMPRA and BPV's marketing practices directed toward specific users and hospitals. Mr. McDermott may also testify concerning IMPRA and BPV's strong corporate policies against off-label marketing. In this regard, Mr. McDermott may testify regarding the measures undertaken by IMPRA and BPV to ensure that employees of the companies did not market any product off-label. Moreover, Mr. McDermott may also testify concerning specific actions taken by IMPRA and BPV if and when they discovered off-label marketing.

Mr. McDermott may also testify concerning IMPRA and BPV's regulatory strategies and polices. In this regard, Mr. McDermott may testify concerning IMPRA and BPV's strategies to gain FDA clearance for the Recovery® Filter and G2® Filter. Mr. McDermott may also testify concerning the communications between

IMPRA and BPV and the FDA. In this regard, Mr. McDermott may testify concerning IMPRA and BPV's vigilant efforts keep the FDA abreast of complications, product improvements and new product generations, and potential changes to IFUs for the Recovery® Filter and G2® Filter. This may include testimony concerning specific communications initiated by IMPRA and BPV to keep the FDA fully informed. Mr. McDermott may also testify regarding IMPRA and BPV's broader communication policies with the FDA.

Mr. McDermott may also testify concerning IMPRA and BPV's practices and policies regarding complaints. In this regard, Mr. McDermott may testify concerning the steps taken by IMPRA and BPV to ensure that the companies adhered to federal reporting requirements. Moreover, Mr. McDermott may testify regarding other procedures and policies undertaken by IMPRA and BPV to gather data regarding complications to the filter products, including, but not limited to, fracture, migration, perforation, and tilt. Mr. McDermott may also testify concerning other steps taken by IMPRA and BPV to ensure that they appropriately responded to complications.

Mr. McDermott may also testify concerning IMPRA and BPV's policies concerning monetary gifts and agreements to fund medical studies. He may also testify concerning how these policies reflect IMPRA and BPV's resolve to ensure that any gift or agreement complies with federal regulation.

22. Chad Modra

Current employee of BPV

May be contacted c/o Nelson Mullins Riley & Scarborough LLP 2017 17th Street, NW, Atlanta GA 30363

See description below.

23. Adrian Ravenscroft

Former employee of NMT May be contacted c/o Nelson Mullins Riley & Scarborough LLP 201 17th Street, NW, Atlanta, GA 30363

Mr. Ravenscroft is a former employee of NMT who worked on the Recovery® Filter development team from 1996 to 1999. In this position, Mr. Ravenscroft developed the patent for the Recovery® Filter and oversaw product development occurring during the time of his employment. He may provide general testimony regarding mechanical engineering and specific testimony regarding product design, technology development, and materials testing. Mr. Ravenscroft was deposed in a separate action involving claims related to Bard's IVC filters on October 21, 2010. Mr. Ravenscroft may testify live or by deposition consistent with his prior deposition testimony.

Specifically, Mr. Ravenscroft may testify about design modification and design validation studies conducted concerning the Recovery® Filter. He may also testify about fatigue endurance testing performed with regard to the Recovery® Filter. Finally, Mr. Ravenscroft may testify about nitinol, its chemical and biomechanical properties, and the effects of electropolishing and other surface

conditioning. He may also testify in general about the history and use of electropolishing for IVC filters.

24. Gin Schulz

Former employee of BPV May be contacted c/o Nelson Mullins Riley & Scarborough LLP 201 17th Street, NW, Atlanta, GA 30363

Ms. Schulz was an employee of C. R. Bard. She was with the company from 2005 until she retired in 2018. At the time of her retirement she was Staff Vice President of Quality Assurance Operations at C. R. Bard. Prior to working in this capacity, she worked for BPV as a Vice President of Quality Assurance. Ms. Schulz may testify live at trial regarding any and all aspects of Bard's quality control processes that are in place or that have been in place for Bard's retrievable IVC filters. Ms. Schulz may testify regarding Bard's processes and procedures for adverse complaint handling, complaint investigation, and reporting of adverse events to the FDA regarding its filters.

Based on reports received by Bard, she may also testify regarding the rates of complications with Bard's IVC filters and any analysis performed by Bard regarding adverse event rates. Ms. Schulz may also testify that the complication rates with Bard's commercially available filters (whether fracture, migration, perforation, or tilt) remain below the guidelines established by the Society of Interventional Radiologists and Bard's action limits. She may also testify that, upon receiving reports of adverse events, Bard was and has been proactive in investigating those

reports and analyzing whether the risk of fracture for its products is in line with industry standards and guidelines, which it is and always has been. She may testify live or by deposition and may also provide testimony that was the subject of her prior deposition testimony.

25. Alex Tessmer

May be contacted c/o Nelson Mullins Riley & Scarborough LLP 201 17th Street, NW, Suite 1700, Atlanta, GA 30363 404-322-6000

Mr. Tessmer is a product Manager at BPV. Mr. Tessmer was previously employed by BPV as an engineer between 1997 and June 2005. In that position, Mr. Tessmer contributed to filter product development occurring during the period 2002 to June 2005. He may provide general testimony regarding mechanical engineering and specific testimony regarding product design, technology development, and materials testing. He may also provide testimony that was the subject of his previous deposition testimony and trial testimony, including testimony in the MDL.

26. Scott Trerotola, M.D.

Consultant to BPV
May be contacted c/o Nelson Mullins Riley & Scarborough LLP
2017 17th Street, NW, Atlanta GA 30363

Dr. Trerotola is an interventional radiologist who is a graduate of the University of Pennsylvania School of Medicine. He did his residency in radiology and fellowship in interventional radiology at Johns Hopkins Hospital. In the past, he served as Director of Interventional Radiology at Indiana University. Currently

he has a clinical practice in interventional radiology and serves as Chief of Interventional Radiology at the University of Pennsylvania Medical Center.

Dr. Trerotola has long experience in the use of IVC filters. He, and/or his practice partners, have been involved in several clinical trials involving IVC filters. He has written articles about IVC filters. Dr. Trerotola has consulted with Bard regarding the design and development of the Recovery® Filter and participated in an animal study regarding the Recovery® Filter. He may discuss the conduct and results of his clinical experience with, and study of, IVC filters, both in general and specifically as to Bard's IVC filters. He has been a consultant for Bard assisting in training and informing other physicians regarding the use of Bard's IVC filters and has assisted Bard in presenting information to the FDA regarding Bard IVC filters. Dr. Trerotola was deposed in a separate action involving claims related to Bard's IVC filters on November 15, 2010. Dr. Trerotola may testify live or by deposition consistent with his deposition testimony.

Additionally, Dr. Trerotola may testify regarding his clinical experience with IVC filters such as his experience with and techniques for placing and retrieving IVC filters, as well as indications for the use of IVC filters. He may also testify regarding the advantages of retrievable IVC filters. He may discuss the benefits, risks, and potential complications of IVC filters, such as migration, fracture, and perforation, and the imaging and other evaluation of those events and their clinical

significance, if any. He may also discuss the dynamic nature of the IVC as well as the body's reaction to and endothelialization of IVC filters.

27. Doug Uelmen

May be contacted c/o Nelson Mullins Riley & Scarborough LLP 201 17th Street, NW, Suite 1700, Atlanta, GA 30363 404-322-6000

Mr. Uelmen was employed by Bard from 1996 to 2005 as Vice President for Quality Assurance. Prior to working in that capacity, Mr. Uelmen was BPV's Director of Quality Assurance. Mr. Uelmen may testify regarding any and all aspects of Bard's quality control processes that are in place or that have been in place for Bard's IVC filters. Mr. Uelmen may testify regarding Bard's processes and procedures for adverse complaint handling, complaint investigation, and reporting of adverse events to the FDA regarding its filters. He may also provide testimony that was the subject of his previous deposition testimony.

28. Carol Vierling

Former employee of BPV May be contacted c/o Nelson Mullins Riley & Scarborough LLP 201 17th Street, NW, Atlanta, GA 30363

Ms. Vierling is a former employee of BPV who held the position of Director of Regulatory Affairs from 1992 through June 2002. In that position, Ms. Vierling was involved with the Recovery® Filter and the regulatory path undertaken to bring that product to the market, and she may testify regarding the same. Ms. Vierling may also testify regarding her understanding of the Asch clinical trial regarding the

Recovery® Filter. Moreover, Ms. Vierling may also testify concerning the regulatory options considered by BPV when it determined the best approach to gain FDA clearance for its new product. In this regard, Ms. Vierling may also testify regarding BPV's communications with the FDA regarding the Recovery® Filter.

Ms. Vierling may also testify regarding the 510(k) submission submitted by Bard to the FDA for the Recovery® Filter in 2002. In this regard, she may testify regarding her signing of the Truthfulness and Accuracy Statement included in that submission. She may also testify regarding the cover letter to the FDA that accompanied the 510(k) submission, why it identified Kay Fuller as the new FDA contact person for this device, how she signed that cover letter, and why she signed the cover letter in the manner that she did. She may also testify to her interactions with Kay Fuller and that Ms. Fuller never expressed any concerns to her regarding the Recovery® Filter 510(k) submission, the testing of that device, the safety or efficacy of that device, or the Asch clinical study regarding that device. She may also provide testimony that was the subject of her previous deposition testimony.

29. Natalie Wong

Current employee of BPV May be contacted c/o Nelson Mullins Riley & Scarborough LLP 201 17th Street, NW, Atlanta, GA 30363

Ms. Wong is an employee of BPV. She began working for the company in 2002. She is currently the Quality Engineering Manager for Bard Biopsy Division. Prior to working in this capacity, she worked for BPV as a Quality Engineering

Manager in Field Assurance, and before that, she worked as a Senior Quality Engineer. Ms. Wong was deposed in a separate action involving claims related to Bard's IVC filters on September 21, 2010. Ms. Wong may testify live or by deposition consistent with her deposition testimony.

Ms. Wong may testify regarding any and all aspects of Bard's quality control and field assurance processes that are, or have been, in place for Bard's IVC filters. Ms. Wong may testify regarding Bard's processes and procedures for adverse complaint handling, complaint investigation, trending analysis, root cause analysis, data integrity audits, and design failure mode analysis relating to Bard's IVC filters.

Based on reports received by Bard, she may also testify regarding the rates of complications with Bard's IVC filters and analyses performed by Bard regarding adverse event rates. Ms. Wong may also testify that the complication rates reported to Bard remain below the guidelines established by the Society of Interventional Radiologists and Bard's action limits. Ms. Wong may also testify regarding Bard's processes and quality control measures used in auditing vendors who supply components and raw materials used to manufacture IVC filters.

Ms. Wong may also testify regarding the evolution of the Bard filters, including the fact that Bard is constantly striving to improve the design and performance of those devices. She may also testify that, upon receiving reports of adverse events, Bard was, and has been, proactive in investigating those reports and

analyzing whether the risk of fracture for its products is in line with industry standards and guidelines. Ms. Wong's testimony on these matters will be consistent with documents that have been produced by Bard.

30. Records Custodians

Bard may call records custodians for each or any of Plaintiff's physicians, hospitals, pharmacies, other care centers or medical providers listed in this Disclosure Statement or Plaintiff's Disclosure Statement, employment records and any other non-party records that have been disclosed during discovery.

- **31.** Any of Plaintiff's other treating physicians and associated staff not already identified who may testify regarding issues of her care, treatment, and alleged damages.
- **32.** Any other witnesses deposed or who will be deposed in this action; in other IVC filter cases; in the MDL, including in *Barraza*, *et al. v. C. R. Bard, Inc.*, United States District Court of Arizona, Case No: 2:16-cv-01374-DGC ("Barraza")

The names listed above should not be construed as an admission that any or all of the facts known to the individuals listed are legally relevant or admissible. Bard reserves all rights to raise appropriate legal challenges to the admissibility of their testimony.

II. Bard's Rule 26(a)(2)(B) Disclosures

Bard previously produced the expert reports for the following retained or specifically employed expert witnesses:

A. Case-Specific Expert Witnesses:

1. Piotr Sobieszczyk, M.D.

Cardiovascular Division Vascular Medicine Section Brigham and Women's Hospital 75 Francis Street Boston, MA 02115

Dr. Sobieszcyzk is board certified in Internal Medicine with subspeciality certification in Cardiovascular Diseases and Interventional Cardiology as well as in Vascular Medicine and Vascular Interventional Medicine. He attended medical school at Columbia University in New York City. He completed his residency in internal medicine at Massachusetts General Hospital in Boston and his fellowship in Cardiovascular Diseases at the Brigham and Women's Hospital in Boston. In the course of his fellowship, he trained in general cardiology and vascular medicine, and subsequently completed his training in interventional cardiology. He is a diplomate of the American Board of Internal Medicine and the American Board of Vascular Medicine. He maintains his clinical practice at Brigham and Women's Hospital in Boston. His clinical practice encompasses medical and interventional treatment of cardiovascular diseases, including coronary and valvular heart disease, peripheral arterial and venous disease and thrombophilia states. He is an instructor at Harvard Medical School.

His qualifications and opinions, and the bases for his opinions, are disclosed in his expert reports and his deposition.

2. Dr. David L. Fischman, M.D., FACC, FACP, FSCA

Thomas Jefferson University Hospital Angioplasty Center 111 S. 11th Street, Suite 6210 Gibbon Building Philadelphia, PA 19107

Dr. Fischman attended New York Medical College. He did his residency in internal medicine at North Shore University Hospital and Memorial Sloan Kettering Cancer Center in New York. He completed his Fellowship in Clinical Cardiology Cardiology Thomas Jefferson and Interventional at the University Hospital/Jefferson Medical College in Philadelphia where, since 1991, he has practiced as an invasive/interventional cardiologist and served on the faculty of the medical college. He has extensive experience treating a wide variety of cardiac conditions. Dr. Fischman's qualifications and opinions, and the basis of his opinions, are disclosed in his expert report and his deposition.

B. Non-Case-Specific Expert Witnesses

Bard discloses for use in this litigation the subject matter of testimony, substance of the facts and opinions, and the opinions and grounds thereof, and qualifications of all experts disclosed by them in the MDL *Barraza* and Bard IVC Filter MDL trial testimony¹:

¹ See Branch v. C.R. Bard, Inc., et al., United States District Court for the Northern District of Texas, Civil Action No. 3:19-cv-02130-S (case tried in July 2021); Wright v. C.R. Bard, Inc., et al., United States District Court for the Northern District of Texas, Civil Action No. 3:19-cv-02176-S (case tried in May 2021); Laloli v. C.R. Bard, Inc., et al., United States District Court for the Northern District of California, Civil Action No. 4:19-cv-05679 (case tried in August 2021); Johnson v. C.R. Bard, Inc., et al., United States District Court for the Western District of Wisconsin, Civil Action No. 3:19-cv-00760 (case tried in June 2021); Peterson v. C.R. Bard, Inc., et al., United States District Court for the District of Oregon, Civil Action No. 3:19-cv-01701 (case tried in May 2021); Ocasio v. C.R. Bard, Inc.,

1. Christine L. Brauer, Ph.D.

Brauer Device Consultants, LLC 7 Trail House Court Rockville, Maryland 20850

Dr. Brauer is an expert in the field of regulatory affairs. Dr. Brauer's qualifications and opinions and the basis of her opinions are disclosed in her expert reports dated April 13, 2017, May 10, 2017, and July 17, 2018, in the Bard IVC filter MDL, her expert report dated July 17, 2018, in the Arizona consolidated *McMahill* action, and are also expected to be consistent with her deposition taken in the MDL and her trial testimony in the IVC filter litigation.²

2. Paul Briant, Ph.D., P.E.

Exponent 149 Commonwealth Drive Menlo Park, CA 94025

Dr. Briant is a mechanical engineer who specializes in mechanical engineering, solid mechanics, and finite element analysis (FEA) of structures, including medical devices. He is a Principal Engineer with Exponent, Inc. Dr. Briant's qualifications and opinions and the basis of his opinions are disclosed in his expert reports dated April 14, 2017, and May 2017 in the Bard IVC filter MDL, his expert report dated March 17, 2017, in the *Barraza* action, his expert report dated July 18, 2018, in the Arizona consolidated *McMahill* action. His opinions are also

et al., United States District Court for the Middle District of Florida, Civil Action No. 8:13-cv-1962 (case tried in July 2021); Craig Couturier v. C. R. Bard, Inc. and Bard Peripheral Vascular, Inc., United States District Court, Eastern District of Louisiana, New Orleans Division, Civil Action No. 2:19-cv-12497(case tried in July 2021).

² See id.

expected to be consistent with his depositions and trial testimony in the IVC filter litigation.³

3. Audrey Fasching, Ph.D., P.E.

Anamet, Inc. 26102 Eden Landing Road, Suite 3 Hayward, CA 94545

Dr. Fasching is a metallurgical engineer with more than twenty years' experience in the areas of failure analysis, welding, heat treatment, corrosion and materials selection. She is a Senior Materials Engineer at Anamet, Inc. Dr. Fasching's qualifications and opinions and the basis of her opinions are disclosed in her expert reports dated April 14, 2017, and May 11, 2017 in the Bard IVC filter MDL, in her expert report dated March 16, 2017, in the *Barraza* action, and in her expert report dated July 18, 2018, in the Arizona consolidated *McMahill* action, and are also expected to be consistent with her depositions taken in the MDL on June 26, 2017, and August 3, 2017.

4. David W. Feigal, M.D.

11806 Barranca Road Santa Rosa Valley, CA 93012

Dr. Feigal is Board Certified in Internal Medicine and has a Master's Degree in Public Health in the fields of epidemiology and biostatistics. Dr. Feigal's qualifications and opinions and the basis of his opinions are disclosed in his expert

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³ See id.

report dated April 13, 2017, in the Bard IVC filter MDL, in his expert report dated March 17, 2017, in the *Barraza* action, and in his expert report dated July 27, 2018, in the Arizona consolidated *McMahill* action. In addition, Bard refers Plaintiff to Dr. Feigal's Supplemental Reliance List to his MDL report dated August 15, 2018. His opinions are also expected to be consistent with his depositions and trial testimony in the IVC filter litigation.⁴

5. Clement J. Grassi, M.D., FSIR 18 Sussex Road Winchester, MA 01890

Dr. Grassi is a medical doctor and is a Fellow of the Society of Interventional Radiology. He is certified in Radiology by the American Board of Radiology, and he holds a Certificate of Added Qualifications in Vascular and Interventional Radiology. Dr. Grassi's qualifications and opinions and the basis of his opinions are disclosed in his expert reports dated April 12, 2017, in the Bard IVC filter MDL, and in his expert report dated March 15, 2017, in the *Barraza* action. His opinions are also expected to be consistent with his depositions and trial testimony in the IVC filter litigation.⁵

6. Christopher S. Morris, M.D.

Department of Radiology The University of Vermont Medical Center 111 Colchester Avenue Burlington, VT 05401

⁴ See id.

⁵ See id.

Dr. Morris is currently an Attending Radiologist at the University of Vermont Medical Center and has more than two decades of clinical experience at a busy tertiary care referral center, including the placement and retrieval of IVC filters, and care and management of patients with IVC filters. Dr. Morris's qualifications and opinions, and the basis of his opinions, are disclosed in his expert report dated April 13, 2017, in the Bard IVC filter MDL, his expert report dated March 16, 2017, in the *Barraza* action, and in his expert report dated June 3, 2019, in the Arizona consolidated *McMahill* action. His opinions are also expected to be consistent with his depositions and trial testimony in the IVC filter litigation.⁶

7. Ronald A. Thisted, Ph.D.

Office of the Provost The University of Chicago Levi Hall, Room 432 5801 South Ellis Avenue Chicago, Illinois 60637

Dr. Thisted is a Professor in the Department of Public Health Sciences, the Department of Statistics, the Department of Anesthesia & Critical Care, the Undergraduate College, and the Committee on Clinical Pharmacology and Pharmacogenomics at the University of Chicago. He is an expert in the fields of statistics, biostatistics, mathematics, and epidemiology. Dr. Thisted's qualifications and opinions and the basis of his opinions are disclosed in his expert report dated

⁶ See, id.

April 13, 2017, in the Bard IVC filter MDL, and in his expert report dated July 17, 2018, in the Arizona consolidated *McMahill* action. His opinions are also expected to be consistent with his deposition taken in the MDL on July 28, 2017 and his trial testimony in the IVC filter litigation.⁷

8. Donna-Bea Tillman, Ph.D., MPA, FRAPS

Brauer Device Consultants, LLC 7 Trail House Court Rockville, Maryland 20850

Dr. Tillman is an expert in the field of regulatory affairs. Dr. Tillman's qualifications and opinions and the basis of her opinions are disclosed in her expert reports dated April 14, 2017, May 12, 2017, and July 12, 2018, in the Bard IVC filter MDL, in her expert report dated March 10, 2017, in the *Barraza* action, and in her expert report dated July 12, 2018, in the Arizona consolidated *McMahill* action. and in her supplemental report. Her opinions are also expected to be consistent with her depositions taken in the MDL on August 4, 2017. In addition, Bard refers Plaintiff to Dr. Tillman's Supplemental Reliance Lists to her MDL and *Barraza* reports dated May 12, 2017. Her opinions are also expected to be consistent with her depositions and trial testimony in the IVC filter litigation.

⁷ Craig Couturier v. C. R. Bard, Inc. and Bard Peripheral Vascular, Inc., United States District Court, Eastern District of Louisiana, New Orleans Division, 2:19-cv-12497-ILRL-DPC

C. Non-Retained Expert Witnesses:

Treating Physicians

Bard designates each of Plaintiff's treating physicians and other healthcare providers that have been disclosed in either party's Rule 26 Disclosures and/or either party's written discovery responses. Bard specifically notes that these witnesses are fact witnesses. However, to the extent that they are called to testify at trial and, as physicians and other healthcare providers, offer opinion testimony, Bard identifies each as a non-retained expert. Each physician or other healthcare provider may testify regarding his or her background, education and training, qualifications, and experience; his or her conversations with Plaintiff; his or her treatment and management of Plaintiff's condition, including any diagnosis rendered, any analysis of pertinent medical records, medical charts, or other treatment documentation; his or her independent recollection of such treatment as set forth in his or her deposition, to the extent a deposition has been taken; his or her knowledge of and experience with the subject filter and IVC filters; and his or her opinions concerning the cause(s) and/or contributing cause(s) of Plaintiff's health condition(s), the need, if any, for future management of Plaintiff's health condition(s), and the reasonable and necessary medical interventions associated therewith as well as any opinions concerning Plaintiff's prognosis as it relates to the health condition(s) relevant to or associated with the inferior vena cava filter that was implanted in Plaintiff. Each physician or other healthcare provider may testify live or by deposition and offer testimony and opinions consistent with his or her deposition testimony. To the extent that any such physician or other healthcare provider has been or will be deposed, Bard objects to each physician or other healthcare provider testifying beyond his or her deposition testimony. Specifically, Bard designates the following of Plaintiff's treating physicians as non-retained experts pursuant to Rule 26(a)(2)(C)

1. Pooja Bardhan, M.D.

Georgia Cancer Specialists Administrative Annex 1835 Savoy Drive Atlanta GA 30341

Dr. Barhan is a physician, board certified in hematology and internal medicine. She received her medical degree from Kasturba Medical College in Mangalore, India, and completed her residency at University of Connecticut Medical Center and her fellowship at the Moffitt Cancer Center of the University of South Florida. She treated Plaintiff at various times between October 2017 and December 2019. She is expected to testify about her evaluation and management of Plaintiff's hypercoagulable state, and that it is not caused by the Bard IVC filter. She is expected to testify about her recommendation that Plaintiff receive lifelong anticoagulation due to her history of recurrent pulmonary emboli, that she prescribed Coumadin for her, that she has counseled her on issues with non compliance with her Coumadin use and checking of her INR levels, and on healthy lifestyle and

weight loss issues to address her morbid obesity. Dr. Bardhan is expected to testify that Plaintiff has moderate persistent reactive airway disease, not related to the Bard IVC filter.

2. Arum Chervu, M.D.

Vascular Surgical Associates 61 Whitaker Street Suite 2100 Marietta, GA. 30060

Dr. Chervu is a physician, board certified in vascular surgery. He received his medical degree from Cornell University Medical College in New York and his residency and fellowships at University of California at Los Angeles. He treated Plaintiff at times between November 2012 and December 2019. He treated Plaintiff at times between November 2012 and December 2019. He is expected to testify about his evaluation of Plaintiff during this time frame for left leg pain, thigh pain, bilateral leg pain, chest pain and shortness of breath, and her report to him of a history of back pain, and his differential diagnoses of the causes of those conditions. He is expected to testify that she experiences moderate arterial occlusive disease in her left leg and to the causes of same. He is expected to testify about the results of testing he ordered on Plaintiff that showed a metallic density in the proximal right peroneal artery, his confirmation in December 2019 that Plaintiff has no filter fragments in her chest, that the fragment in her right leg is unchanged in appearance from prior studies, and that no intervention is indicated regarding her Bard IVC filter.

3. Stephanie Eaton, M.D.

Pulmonary & Critical Care of Atlanta 960 Johnson Ferry Road NE Suite 500 Atlanta, GA 30342

Dr. Eaton is a physician, board certified in internal medicine, pulmonary diseases and critical care medicine. Dr. Eaton received her medical degree from the University of Southern California at Irvine and did her residency in internal medicine, and her fellowship in pulmonary and critical care, at Emory University Hospital in Atlanta, Georgia. Dr. Eaton is expected to testify regarding her treatment of Plaintiff between 2003 and 2008, including her recommendation in September 2004 that an IVC filter be placed in Plaintiff when anticoagulation therapy for Plaintiff failed and Plaintiff developed recurrent pulmonary emboli, and the risks and benefits of the IVC filter that she discussed with Plaintiff prior to the filter's She is expected to testify regarding Plaintiff's diagnosis of a placement. hypercoagulable state (Factor V Leiden deficiency), Plaintiff's need for continued use of anticoagulants and an IVC filter, Dr. Eaton's treatment of Plaintiff for chest pain, and chronic fatigue, exertional dyspnea, potential pulmonary hypertension, and pericardial effusion with respiratory failure and subsequent paralyzed left hemidiaphragm that she does not relate to the IVC filter. Dr. Eaton is expected to testify consistent with the deposition testimony she provided in this case.

4. Jason Levy, M.D.Northside Radiology

1000 Johnson Ferry Rd. Atlanta, GA 30342

Dr. Levy is a physician, board certified in interventional radiology. He received his medical degree from Washington University in St. Louis, Missouri, and did his internship and fellowship in radiology at Lenox Hill Hospital and Mallinckrodt Institute of Radiology in New York. He has practiced as an interventional radiologist in Atlanta, Georgia since 2001, and presently practices through Northside Hospital. He is a member of the Society of Interventional Radiologists. Dr. Levy is expected to testify that the Bard IVC filter was prescribed for Plaintiff to protect her from recurrent pulmonary emboli which she had experienced, despite being treated with anticoagulants. He is expected to testify about the risk benefit analysis he performed prior to implanting the filter in Plaintiff, the information he provided Plaintiff about the filter, the procedure he utilized to implant the filter and the position of the filter once placed by him in 2004. He is also expected to testify about his knowledge prior to implanting the filter in Plaintiff of the risks and benefits of IVC filters. Dr. Levy is also expected to testify about his 2012 evaluation of imaging performed on Plaintiff, at the request of other physicians, during which he determined that there was a filter strut in her heart, and that he recommended further evaluation of that finding by her cardiologists. He is expected to testify that, following his 2012 evaluation of Plaintiff's filter, he recommended that an attempt be made to percutaneously retrieve the filter body from Plaintiff's

IVC. Dr. Levy is expected to testify consistent with the deposition testimony he provided in this case.

5. John Murray, M.D.

Emory Pulmonology Clinic 555 Peachtree St Medical Office Tower Floor 15 Atlanta, GA 30308

Dr. Murray is a physician, board certified in pulmonology. He practices at Emory University Hospital in Atlanta, Georgia. Dr. Murray evaluated Plaintiff in November 2018 for shortness of breath on exertion, fatigue, and other conditions. He is expected to testify that the causes of those conditions are multifactorial in a setting of deconditioning and morbid obesity, and that cardiac and pulmonary testing performed on Plaintiff at that time revealed no abnormalities.

6. John D. Puskas, M.D.

Icahn School of Medicine at Mount Sinai Beth Israel Hospital 1111 Amsterdam Ave New York, NY 10025

Dr. Puskas is a physician, board certified in general surgery and cardiothoracic surgery. He received his medical degree from Harvard University Medical School and his fellowship in cardiothoracic surgery from Emory University. From 1993 to 2014 he practiced at Emory University Hospital in Atlanta, Georgia. He presently practices at Mount Sinai Beth Israel Hospital in New York City. He saw Plaintiff in November 2012 for a consultation regarding her IVC filter, ordered and reviewed various cardiac testing performed on Plaintiff in December 2012, and reported that

Plaintiff had no filter fragment in her heart, no cardiac findings of significance, and that she required no surgical intervention relative to the IVC filter. Dr. Puskas is expected to testify consistent with the deposition testimony he provided in this case.

7. John Sparti, D.O.

Dallas Family Practice Center 318 Main St Dallas, GA 30132

Dr. Sparti is an osteopathic physician who received his training at the Kansas City College of Osteopathic Medicine in Kansas City, Missouri. He practices family medicine as a primary care physician in Dallas, Georgia. He treated Plaintiff between 2017 and 2020. Dr. Sparti is expected to testify to his treatment of Plaintiff for management of her anticoagulant medication prescribed for her Factor V Leiden deficiency, as well as about his treatment relating to her morbid obesity, hypertension, back pain, fatique and anxiety, and his opinions as to the causes of those conditions. Dr. Sparti is expected to testify consistent with the deposition testimony he provided in this case.

Bard Employees or Former Employees

Bard further designates the following of its current or former employees as non-retained experts: Rob Carr, Andre Chanduszko, John DeFord, Chad Modra, Shari O'Quinn. These witnesses may be called to testify to offer opinions, some of which may constitute expert opinions on certain matters within their knowledge, experience, review of literature, and training. They may be called to testify and

refute Plaintiff's allegations and the opinions of Plaintiff's experts. These witnesses will not offer case-specific opinion testimony, but rather each witness may testify consistent with any previous deposition and/or trial testimony.⁸

1. Robert Carr

May be contacted c/o Nelson Mullins Riley & Scarborough LLP 201 17th Street NW, Suite 1700, Atlanta, GA 30363 (404) 322-6000

Mr. Carr is currently Vice President, Project Management at BPV. Mr. Carr previously held the position of Director of Research and Development with responsibility for IVC filters. Prior to joining BPV in 2002, Mr. Carr was employed by Nitinol Medical Technologies ("NMT"), where he was also responsible for that company's research and development of IVC filters. Mr. Carr may provide testimony regarding biomedical and biomechanical engineering generally, as well as testimony regarding the design, development, manufacture, testing, clearance, evolution, and use of Bard filters, specifically. Mr. Carr may also respond to and rebut claims made by Plaintiff. Mr. Carr may testify live or by deposition consistent with his prior deposition testimony and trial testimony, including in the MDL as well as cases that were remanded from the MDL and tried in various federal district courts.⁹

⁸ See id.

⁹ See id.

Additionally, Mr. Carr may testify regarding the fact that at the time Bard's IVC filters were developed and first sold, and even today, there was and still is a dearth of scientific information about the internal functioning of the IVC. As a result, Bard engineers had to make novel assumptions regarding the forces caused by both blood flow and clotting in the IVC, in order to test the device's migration resistance, potential for fracture, and other potential complications. Those assumptions were supported by expert clinical advisors, by animal testing, and by applicable scientific literature.

The FDA cleared the Recovery® and G2® filters to enter the market after a rigorous review and analysis of the data, trials, and testing of the products. Such testing included, but was not limited to, abdominal pressure and respiration simulation tests, cyclical arm and diaphragmatic tests, fatigue life simulations, radial strength tests, hook strength tests, weld integrity tests, simulated use testing, and migration resistance testing. The Recovery® and G2® filters passed all such tests. Mr. Carr also may testify about the design features of each of Bard's filters and the evolution of those designs. He may testify about NMT's and Bard's design and product verification and validation processes. He may testify about NMT's and Bard's bench and other testing of its filter products, including without limitation fatigue and migration related testing, the protocols for certain of those tests, the

modifications to testing protocols for certain of those tests, and the results of certain of those tests, as well as the clinical trials relating to those filters.

Mr. Carr may also testify regarding potential alternative designs of IVC filters, the risks and benefits of various alternative designs, and the various risks and benefits of competitor IVC filters.

Mr. Carr may also testify regarding the fact that, in the medical literature and medical community, it is understood that, as with all IVC filters, the use of Recovery® and G2® filters carries with it certain risks, including the risk of fracture, migration, perforation, tilt, and embolization, such that each doctor is to weigh the risks and benefits of implanting the device based on each individual patient's medical condition and treatment needs. The reported fracture, migration, perforation, and embolization rates of Bard's commercially available filters remain below the guidelines established by the Society of Interventional Radiologists and Bard's action limits. Bard was and has been proactive in investigating reports of complications with its filters and analyzing whether the reported rate of complications for its products are in line with industry standards regarding reported rates, which it is and always has been. At all times, Bard has kept the FDA abreast of the information it has about complications and complication reporting rates with the Recovery® and G2® Filters. In fact, the FDA has praised Bard for its openness and transparency in sharing information about its products.

Mr. Carr may also testify regarding the evolution of the Bard filters, including the regulatory history of Bard's filters, rates of reported adverse events of Bard's filters, the fact that Bard is constantly evaluating the medical devices it sells, and it is constantly striving to improve the performance of those devices. As part of that process, Bard developed the G2®, G2 Express®, G2®X, EclipseTM, Meridian®, and Denali® filters. Mr. Carr may testify that, subsequent to the introduction of the G2® Filter, Bard introduced the G2 Express® (aka G2®X Filter) and then, the Eclipse™, the Meridian®, and, more recently, the Denali® filters. He will also testify regarding various IVC filter projects that Bard attempted over the years, including those such as the G3 and G2® Platinum. He will also testify to the various timelines and challenges each filter generation and various projects that were not successful. He will also testify regarding the challenges and Bard's knowledge relative to working within the IVC.

In addition, Mr. Carr may also testify regarding the consideration Bard gave to the issue that surface conditions may have played a role in filter fractures, including a discussion of testing Bard conducted to attempt to determine whether surface condition played any role in fracture. Such testing included fatigue testing, clinical testing, SEM review, material qualifications, and product verification testing including delivery, radial force, and fatigue testing.

Additionally, Mr. Carr may testify regarding the effect, if any, that in-dwell time may have on the incidence of fracture in filters. Such testimony may include discussion and analysis of medical literature and anecdotal reports on this topic.

Mr. Carr may also testify regarding his experience, analysis, and involvement with the study conducted in 2002 by Dr. Murray Asch. Specifically, Mr. Carr may testify that the Asch study was approved by Mt. Sinai Hospital and by the Canadian Authority that is equivalent to the FDA, that Dr. Asch conducted his study in accordance with the requirements of his hospital and the Canadian authorities, that he selected the patients to receive Bard Recovery® filters, and that he determined when and which patients in the study would have their filters retrieved. Mr. Carr's testimony may also discuss that Dr. Asch implanted Recovery® filters in 60 patients and experienced one migration (Patient #9) and one fracture (Patient #33) which Bard investigated (with input from Dr. Asch). Mr. Carr may also testify that Bard provided Dr. Asch with all information that he, his hospital, or the Canadian authorities requested relative to these two events, that Dr. Asch was approved to continue the study, and that Dr. Asch reported excellent ease of implantation, lack of complications, and ease and success of retrieval. Mr. Carr may further testify regarding his experience, analysis, and involvement with the EVEREST clinical trial relating to the G2® filter.

Mr. Carr may further testify about the procedures followed by Bard to inspect and confirm the quality of the various materials (including nitinol wire) used to manufacture the IVC filters. Mr. Carr may also testify regarding Bard's processes for verifying the integrity and design of component parts and products supplied by various other companies, Bard's materials verification processes, the selection and auditing of vendors, routine testing done as part of the manufacturing process, internal and external audits of Bard's plants, and the manufacturing plant's role in product complaint investigation. Mr. Carr may also testify about Bard's interaction and relationship with certain doctors who have consulted with Bard about IVC filters. He may also testify concerning caudal migration associated with the G2® filter, including reports that Bard received about caudal migration, investigations that Bard undertook concerning caudal migration, actions taken concerning caudal migration, and communications that Bard made concerning caudal migration.

He may also provide testimony that was the subject of his previous deposition testimony or the subject of declarations/affidavits he has submitted in this action, in the MDL and his testimony in other IVC filter trials that were remanded from the MDL and tried in various federal district courts¹⁰. Mr. Carr's testimony on these matters will be consistent with his opinion that the Bard IVC filters were appropriately designed, evaluated, and tested.

¹⁰ See id.

2. Andre Chanduszko

May be contacted c/o Nelson Mullins Riley & Scarborough LLP 201 17th Street NW, Suite 1700, Atlanta, GA 30363 404-322-6000

Mr. Chanduszko is an employee of BPV working as a staff engineer with responsibilities related to the design, development, and testing of IVC filters. Prior to coming to BPV in 2004, he worked as a general engineer with NMT where he worked with the Simon Nitinol® filter and on the development and testing of what would become the Recovery® filter. Mr. Chanduszko may provide testimony regarding biomedical and biomechanical engineering generally, as well as testimony regarding the design, development, manufacture, testing, clearance, evolution, and use of Bard filters, including rates of reported adverse events of Bard's filters. Mr. Chanduszko may also respond to and rebut claims made by Plaintiff. Mr. Chanduszko may testify live or by deposition consistent with his prior deposition testimony and trial testimony, including in the MDL as well as cases that were remanded from the MDL and tried in various federal district courts. 11

Additionally, Mr. Chanduszko may testify regarding the fact that at the time the Recovery® Filter was developed and first sold, and even today, there is a dearth of scientific information about the internal functioning of the IVC. As a result, Bard engineers had to make novel assumptions regarding the forces caused by both blood

¹¹ See id.

flow and clotting in the IVC in order to test the device's migration resistance, potential for fracture, and other potential complications. Those assumptions were supported by expert clinical advisors, by animal testing, and by applicable scientific literature. The FDA cleared the Recovery® and G2® filters to enter the market after a rigorous review and analysis of the data, trials, and testing of the products. Such testing included, but was not limited to, abdominal pressure and respiration simulation tests, cyclical arm and diaphragmatic tests, simulated use testing, fatigue life simulations, radial strength tests, hook strength tests, weld integrity tests, and migration resistance tests. The Recovery® and G2® filters passed all such tests.

Mr. Chanduszko may testify regarding the physical and chemical properties of nitinol and the utility and significance of that product in the design of Bard filters. He may testify about the design features of each of Bard's filters and the evolution of those designs. He may testify about NMT's and Bard's design and product verification and validation processes. He may testify about NMT's and Bard's bench and other testing of its filter products, including without limitation fatigue and migration related testing, the protocols for certain of those tests, the modifications to testing protocols for certain of those tests, and the results of certain of those tests.

Mr. Chanduszko may also testify regarding the fact that, in the medical literature and medical community, it is understood that, as with all IVC filters, the use of Recovery® and G2® filters carries with it certain risks, including the risk of

fracture, migration, perforation, tilt, and embolization. He may further testify that the reported fracture, migration, perforation, tilt, and embolization rates of Bard's commercially available filters remain below the guidelines established by the Society of Interventional Radiologists and Bard's action limits. Upon receiving reports of fracture and migration, Bard was and has been proactive in investigating those reports and analyzing whether the risk of complications for its products is in line with industry standards, which it is and always has been. At all times, Bard has kept the FDA abreast of the information it has about complications and complication rates with its IVC Filters.

Mr. Chanduszko may testify to Bard's procedures for response to, and investigation of, complaints relating to its filter products, to tests conducted as a part of such investigations, and to the conclusions drawn from such investigations.

Mr. Chanduszko may also testify regarding the evolution of the Bard filters, including the fact that Bard is constantly evaluating the medical devices it sells, and it is constantly striving to improve the performance of those devices. As part of that process, Bard developed the G2®, G2 Express®, G2®X, Eclipse™, Meridian®, and Denali® filters. Mr. Chanduszko may also discuss the effect, feasibility, and any risk or benefit to be gained by improvements in subsequent generation filters. In that regard, Mr. Chanduszko may testify that, subsequent to the introduction of the G2® Filter, Bard introduced the G2 Express® (aka G2®X filter) and then, more recently,

the Meridian®, Eclipse™ and Denali® Filters. He will also testify regarding various IVC filter projects that Bard attempted over the years, including those such as the G3 and G2® Platinum. He will also testify to the various timelines and challenges each filter generation and various projects that were not successful. He will also testify regarding the challenges and Bard's knowledge relative to working within the IVC.

Mr. Chanduszko may also testify regarding the consideration Bard gave to the issue that surface conditions may have played a role in filter fractures, including a discussion of testing Bard conducted to attempt to determine whether surface condition played any role in fracture. Such testing included fatigue testing, clinical testing, SEM review, material qualifications, and product verification testing including delivery, radial force, and fatigue testing.

Mr. Chanduszko may further testify about the procedures followed by Bard to inspect and confirm the quality of the various materials (including nitinol wire) used to manufacture the IVC filters. Mr. Chanduszko may also testify regarding Bard's processes for verifying the integrity and design of component parts and products supplied by various other companies, Bard's materials verification processes, the selection and auditing of vendors, routine testing done as part of the manufacturing process, internal and external audits of Bard's plants, and the manufacturing plant's role in product complaint investigation. Mr. Chanduszko's testimony on these

matters will be consistent with his opinion that the Bard IVC filters were appropriately designed, evaluated, and tested.

3. **John DeFord**

May be contacted c/o Nelson Mullins Riley & Scarborough LLP 201 17th Street NW, Suite 1700, Atlanta, GA 30363 404-322-6000

Dr. DeFord was formerly the Senior Vice President of Science, Technology and Clinical Affairs of C. R. Bard. Dr. DeFord may testify regarding any and all aspects of the design, development, testing, clearance, evolution, and use of Bard filters, including Bard's policies and procedures for design, testing, and evaluation of IVC filters, including the use of and evaluation of medical literature. Dr. DeFord may also provide testimony that was the subject of his deposition testimony, including his deposition specifically taken for preservation of testimony on August 15, 2019 and trial testimony including in the MDL as well as cases that were remanded from the MDL and tried in various federal district courts.¹²

4. Chad Modra

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Mr. Modra is currently the Worldwide Vice President of Quality Management. Mr. Modra may testify regarding any and all aspects of Bard's quality control processes that are in place or that have been in place for Bard's retrievable

¹² *See* id.

IVC filters. Mr. Modra may testify regarding Bard's processes and procedures for adverse complaint handling, complaint investigation, and reporting of adverse events to the FDA regarding its filters.

Based on reports received by Bard, he may also testify regarding the rates of complications with Bard's retrievable IVC filters and any analysis performed by Bard regarding adverse event rates.

Mr. Modra may also testify that the complication rates with Bard's commercially available IVC filters remain below the guidelines established by the Society of Interventional Radiologists and Bard's action limits. He may further testify about Bard's extensive internal processes and training regarding monitoring and reporting of adverse events.

He may also testify that, upon receiving reports of adverse events, Bard was and has been proactive in investigating those reports and analyzing whether the risk of complications for its products is in line with industry standards and guidelines, which it is and always has been.

Mr. Modra may further testify to and respond to any claims that complications for IVC filters are underreported, how underreporting of adverse events have changed over the years, why underreporting rates of adverse events for medical devices in general do not necessarily apply high risk devices, such as IVC filters, and various other factors affecting the reporting or underreporting of adverse events

in general for medica devices and specific to IVC filters, including the Recovery Filter.

Mr. Modra may testify regarding Bard's quality and risk management systems and quality and risk management systems in general. He may further testify about DFMEAs, FEMEAs, and various Bard risk analysis and documents, including those performed by the Company regarding Bard's IVC filters, including the Recovery filter, since Bard's retreivale filters were brought to the market in 2003. He may further testify about risks and benefits of IVC filters. He may further testify about 2008 Surgeons Call to Action to Prevent Deep Vein Thrombosis and Pulmonary Embolism.

If the FDA Warning Letter Bard received in 2015 is determined to be relevant, Mr. Modra may testify about FDA Warning Letters in general and specifically about the FDA Warning Letter issued to Bard in 2015 and Bard's response to same.

Mr. Modra may also testify about matters that were the subject of his deposition and trial testimony including in the MDL as well as cases that were remanded from the MDL and tried in various federal district courts.¹³

¹³ See id.

5. Shari O'Quinn (formerly Shari Allen)

May be contacted c/o Nelson Mullins Riley & Scarborough LLP 201 17th Street NW, Suite 1700, Atlanta, GA 30363 404-322-6000

Ms. O'Quinn is a former employee of BPV who held three different positions while working for BPV, including Manager of Regulatory Affairs, Director of Regulatory Affairs, and Director of Regulatory and Clinical Affairs. In these roles, Ms. O'Quinn was involved with the Recovery® filter and may testify regarding the regulatory history of Bard's filters, rates of reported adverse events of Bard's filters, BPV's decision to revise the IFU for the Recovery® Filter and to disseminate a Dear Doctor Letter in 2004 or the Dear Colleague Letter in 2005. In this regard, Ms. O'Quinn may also testify regarding BPV's communications with the FDA regarding the Recovery® filter. Moreover, Ms. O'Quinn may testify concerning BPV's internal decision-making process regarding if or when to discontinue marketing the Recovery® Filter from the market. Ms. O'Quinn may testify concerning the considerations that BPV analyzed in formulating its decision.

Ms. O'Quinn may also discuss the various regulatory pathways for medical devices to reach the market, the various classifications of medical devices, and the differences between 510(k) and PMA devices. Ms. O'Quinn may also testify about the significance of down-classification of a medical device and the down-classification history relating to IVC filters, including FDA's internal memorandum regarding the same.

Ms. O'Quinn may also testify about clinical studies and why clinical studies, even for permanent-only devices or PMA devices are typically done for a period of one year or less.

She may also provide testimony that was the subject of her previous deposition testimony and trial testimony, including in the MDL, as well as cases that were remanded from the MDL and tried in various federal district courts.¹⁴

To the extent information regarding the G2® Filter is relevant in this litigation, Ms. O'Quinn may testify concerning BPV's overall regulatory strategy for its filter lines, including the regulatory approach taken by BPV concerning the G2® Filter. In this regard, Ms. O'Quinn may testify regarding BPV's decision to file a Special 510(k) for the G2® Filter and its decision to change its submission to a Traditional 510(k). Moreover, Ms. O'Quinn may also testify concerning other regulatory options considered by BPV when it determined the best approach to gain FDA clearance for its new product. Ms. O'Quinn may testify regarding communications between the FDA and BPV concerning the clearance process for the G2® Filter. In this regard, Ms. O'Quinn may testify concerning BPV's decision to initially submit a Special 510(k), the FDA's decision to request clinical data in order to clear a removable indication for the G2® Filter, and any communication between BPV and the FDA concerning these matters. Ms. O'Quinn may also testify

 $^{^{14}}$ See id.

concerning BPV's decision to conduct a clinical trial, the EVEREST Study, the regulatory clearance process associated with that study, and BPV and the FDA's communications regarding that study. Ms. O'Quinn may also testify concerning other issues and events associated with or related to the EVEREST Study. Ms. O'Quinn may also testify concerning caudal migration associated with the G2® Filter, including reports that Bard received about caudal migration, investigations that Bard undertook concerning caudal migration, actions taken concerning caudal migration, and communications that Bard made concerning caudal migration.

Ms. O'Quinn may also testify regarding BPV's representations made to the FDA while it was attempting to gain clearance for the G2® Filter. Ms. O'Quinn may also testify concerning BPV's communications with the FDA regarding reported complications with the Recovery® Filter and the G2® Filter. Ms. O'Quinn may also testify concerning the internal process that BPV undertook to determine when it was appropriate to make such contact with the FDA. Moreover, Ms. O'Quinn may also testify concerning any other communication between the FDA and BPV during the period in which Ms. O'Quinn worked at BPV, to the extent that she has personal knowledge of such communications. In this regard, Ms. O'Quinn may testify regarding meetings and communications between BPV and the FDA concerning BPV's filters and its plans to develop a second generation filter. Ms. O'Quinn may also testify regarding the steps that BPV took to ensure that the FDA was always

abreast of complications, product improvements, and potential changes to IFUs for

the Recovery® Filter and G2® Filter. In this regard, Ms. O'Quinn may testify

regarding BPV's open and frank communications with the FDA and the FDA's

appreciation for BPV's openness and honesty.

Ms. O'Quinn may also testify concerning BPV and Bard's strong corporate

policy against off-label marketing. In this regard, Ms. O'Quinn may testify regarding

the measures undertaken by BPV and Bard to ensure that employees of the

corporations did not market any product off-label. Moreover, Ms. O'Quinn may also

testify concerning specific actions taken by BPV and Bard if and when they

discovered off-label marketing. Ms. O'Quinn may also testify concerning BPV and

Bard's policies concerning monetary gifts and agreements to fund medical studies.

She may also testify concerning how these policies reflect BPV and Bard's resolve

to ensure that any gift or agreement complies with federal regulations.

III. Bard's Reservation of Rights

Bard reserves the right to designate and call as a witness, live or through

deposition, any expert witness designated by another party in this case. Bard reserves

the right to supplement its expert disclosures before trial.

Dated this 18th day of November, 2021.

/s/ Richard B. North, Jr.

Richard B. North, Jr.

Georgia Bar No. 545599

65

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Attorneys for C. R. Bard, Inc. and Bard Peripheral Vascular, Inc.

CERTIFICATE OF SERVICE

I hereby certify that I have served a true and correct copy of Defendants C. R. Bard, Inc.'s and Bard Peripheral Vascular, Inc.'s Rule 26(a)(2) Disclosures this 18th day of November, 2021, via electronic mail and U.S. First Class Mail to the following:

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